REMARKS

Claims 1-26 are in the case. Claims 7-15, 18, 25, and 26 have been withdrawn from the case by the Examiner due to the finality of the Requirement for Restriction and/or the finality of the election of species; Claims 1-6, 16-17, and 19-24 remain under consideration.

Background for addressing the §102 rejections

The remarks here apply to both the §102(a) rejection and the §102(b) rejection made in the present Office Action.

The statement in the Office Action regarding the patentability of a new property of an old composition is not relevant to the present claims, which are directed to methods.

Page 3 of the Office Action correctly states that "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." New uses of known processes are patent-eligible subject matter under 35 U.S.C. §§100 and 101. Section 100 states:

> When used in this title unless the context otherwise indicates -
> (a) The term "invention" means invention or discovery.
> (b) The term "process" means process, art, or method, and **includes a new use of a known process**, machine, manufacture, composition of matter, or material.
> (Emphasis added.)

Therefore, claims to a new use or process utilizing a known compound are cannot be considered automatically *un*patentable. Similarly, as acknowledged in the present Office Action (and stated in M.P.E.P. §2112.02), "[t]he discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using." Thus, whether claims to a particular process utilizing a known compound (or set of known compounds) is to be based on the usual considerations of novelty and nonobviousness, and there is no presumption of *un*patentability for such claims.

Additionally, the specific features of the present claims have been ignored. In particular, Claim 1 is directed to a "method of treating the graying of scalp hair by

administering to a mammal in need of such treatment". Since there is no disclosure of whether the patients in the studies described in the cited references were in need of such treatment, there can be no anticipation. In this connection, the Federal Circuit has stated that "Newly discovered results of known processes **directed to the same purpose** are not patentable because such results are inherent." *Bristol-Meyers Squibb Co. v. Ben Venue Laboratories Inc.*, 246 F.3d 1368, 1376, 58 U.S.P.Q.2d 1508 (Fed. Cir. 2001), quoting *In re May*, 574 F.2d 1082, 1090, 197 U.S.P.Q. 601, 607 (C.C.P.A. 1978) (emphasis added). In *May*, both the claims under consideration and the cited prior art were directed to use of a composition as an analgesic (same composition *for the same purpose*). In the present case, the claims clearly are directed to a *different purpose* than that of either cited reference. Both Bjermer et al. and Malmstrom et al. teach the use of montelukast for treatment of *asthma*; in contrast, the present claims are directed to treatment of *the graying of hair.*

Returning to the concept of an inherent disclosure alluded to above, there are several requirements for a finding of inherency. First, presence or absence of an inherent feature is a fact determination. *In re Grasselli*, 713 F.2d 731, 739, 218 U.S.P.Q. (BNA) 769 (Fed. Cir. 1983). Second, the inherent feature must always be present in the prior art: "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (1981), quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214, 40 U.S.P.Q. 665, 667 (C.C.P.A. 1939). Optimal conditions are not considered to be inherent in the prior art. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993). In other words, the inherent property must be present all the time, not just by selecting certain (optimal) unspecified conditions from the generalized teachings of the cited reference.

Rejection under §102(a) by Bjermer et al.

Claims 1-6, 16-17, and 19-24 stand rejected under 35 U.S.C. §102(a) as anticipated by Bjermer et al., *Respiratory Medicine*, 2000, **94**, 612-621. Applicants respectfully traverses this rejection and requests reconsideration and withdrawal of the same.

Bjermer et al. describes a *proposed* double-blind study of a treatment course of

montelukast (10 mg once per day) in combination with fluticasone propionate (Page 613, under the heading "Study design"). In fact, Bjermer et al. states that "This study will begin with an initial 4-week run" (Page 614, under the heading "Treatment and follow-up"), *i.e.*, the study has not begun, and no data has yet been collected. Because the study described in Bjermer et al. had not been carried out, any effect of montelukast on the graying of hair is at best an unsuspected possibility, and is not an inherent feature of the teachings of Bjermer et al. under the requirements for anticipation as enunciated in, for example, *In re Oelrich, supra.* Thus, since the proposed study of Bjermer et al. had not been carried out at the time of publication and does not inherently show treatment of graying of hair, Bjermer et al. cannot anticipate the present claims.

In addition, Bjermer et al. is not enabling. Enablement is directed those of skill in the art (35 U.S.C. §112, first paragraph). Nothing in the proposed study of Bjermer et al. could direct one of skill in the art to recognize that montelukast could be used for the treatment of the graying of scalp hair in those patients in need of such treatment. Since the study in Bjermer et al. had not been carried out, there was no opportunity for observing changes in the hair color of those patients in the study having graying hair. Because Bjermer et al. is not enabling to one of ordinary skill with respect to the presently claimed invention, this rejection fails to establish a *prima facie* case of anticipation, is improper, and should be withdrawn.

Finally, it should be noted that Applicant is willing to submit an affidavit stating that the invention was made before the publication of Bjermer et al., if such affidavit is necessary to place this case in condition for allowance.

Rejection under §102(b) by Malmstrom et al.

Claims 6, 16-17, and 19-24 stand rejected under 35 U.S.C. §102(a) as anticipated by Malmstrom et al., *Ann. Intern Med.*, 1999, 130, 487-495. Applicants respectfully traverses this rejection and requests reconsideration and withdrawal of the same.

The disclosure of Malmstrom et al. does not anticipate the present claims. Referring to the requirements for inherency described above, Malmstrom et al. does not inherently teach

the use of montelukast for the treatment of the graying of hair. There is nothing in Malmstrom et al. which would definitively show that any study subject was in fact in need of treatment for graying hair. The age range of the study subjects in Malmstrom et al. was 15-78, with a median age of 35 (Page 490, Table 1, under "Montelukast Group"). In other words, as described above, not everyone who needs treatment for asthma also needs treatment for the graying of hair.

To form this rejection, the Office Action focuses on the elderly patients who received montelukast, surmising that they would receive treatment for the graying of hair (Office Action, Page 3, first paragraph). As the selection of optimal conditions (here, the selection of patients in the cited study which were both elderly and further characterized by the graying of scalp hair) is not permitted for inherency rejections, this rejection fails to establish a *prima facie* case of anticipation, is improper, and should be withdrawn.

Furthermore, Malmstrom et al. is not an enabling reference. Enablement is directed those of skill in the art (35 U.S.C. §112, first paragraph). Nothing in Malmstrom et al. directs one of skill in the art to recognize that montelukast could be used for the treatment of the graying of scalp hair in those patients in need of such treatment. This rationale was one of the reasons for finding a reference non-enabling in *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, 545 F.3d 1312, 88 U.S.P.Q.2d 1381 (Fed. Cir. 2008). In fact, Malmstrom et al. notes that "No statistically significant ($P > 0.05$) treatment-by-subgroup interactions were seen," suggesting that changes in the hair color of those patients with graying hair were not observed. Because Malmstrom et al. is not enabling to one of ordinary skill with respect to the presently claimed invention, this rejection fails to establish a *prima facie* case of anticipation, is improper and should be withdrawn.

Favorable action on all of the pending claims is thus solicited. If any matter remains unresolved which may be resolved without the need for a formal action, the Examiner is invited to contact the undersigned.

Respectfully submitted,

McGLINCHEY STAFFORD, PLLC

/R. Andrew Patty II/
R. Andrew Patty II
Reg. No. 38,992
Attorney of Record
301 Main Street, 14th Floor
Baton Rouge, LA 70802
Telephone: (225) 383-9000
Facsimile: (225) 343-3076